

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**SPECIAL INTEREST TOPIC**

**TITLE: TREATMENT IND LIST ALLOWED TO  
PROCEED**

**DATE: JUNE 22, 1987- MARCH 27-1998**

**TREATMENT INVESTIGATIONAL NEW DRUGS (INDS)  
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<b><u>DRUG</u></b>	<b><u>SPONSOR</u></b>	<b><u>EFFECTIVE DATE</u></b>
<b>Cytomegalovirus Immune Globulin</b>  <u>Indication</u> - To prevent cytomegalovirus infections in certain renal transplant patients. [Charges]	Commonwealth of Massachusetts Department of Public Health	10-19-87
<b>Ifosfamide &amp; Mesna</b>  <u>Indication</u> - Refractory germ cell carcinoma (mesna protects the bladder from toxicity associated with ifosfamide treatment).	National Cancer Institute	12-24-87
<b>Trimetrexate</b>  <u>Indication</u> - Pneumocystis carinii pneumoinia in AIDS patients who cannot tolerate standard forms of treatment.	National Institute of Allergy & Infectious Diseases	02-18-88
<b>Anafranil (Clomipramine HCl)</b>  <u>Indication</u> - Treatment of severe obsessive compulsive disorder.	Ciba-Geigy	06-03-88
<b>Eldepryl (Selegiline HCl)</b>  <u>Indication</u> - Treatment of severe Parkinson's disease unresponsive to standard therapy. [Charges]	Somerset Pharmaceuticals	06-16-88
<b>Pentostatin</b>  <u>Indication</u> - Treatment of hairy cell leukemia refractory to alpha interferon.	National Cancer Institute	07-28-88

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<b>Teniposide</b>  <u>Indication</u> - Treatment of relapsed or refractory acute lymphoblastic leukemia.	National Cancer Institute	10-07-88
<b>Ganciclovir</b>  <u>Indication</u> - Treatment of cytomegalovirus retinitis in AIDS patients.	National Institute of Allergy & Infectious Diseases	11-28-88
<b>Pentamidine Isethionate Aerosolized</b>  <u>Indication</u> - Prevention of Pneumocystis carinii pneumonia in AIDS patients. [Charges]	LyphoMed Inc.	02-03-89
<b>Levamisole hydrochloride</b>  <u>Indication</u> - For use (with 5-fluorouracil) as an adjuvant treatment for Dukes C adenocarcinoma of the colon.	National Cancer Institute	05-04-89
<b>Erythropoietin (EPO)</b>  <u>Indication</u> - Treatment of zidovudine (AZT) related anemia in HIV positive patients.	Ortho	06-27-89
<b>Exosurf (synthetic pulmonary surfactant)</b>  <u>Indication</u> - Prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.	Burroughs Wellcome	07-26-89

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<b>Dideoxyinosine (ddI)</b>  <u>Indication</u> - Treatment of patients with AIDS or AIDS Related Complex who are intolerant to zidovudine (AZT).	Bristol-Myers	09-28-89
<b>Survanta (bovine pulmonary surfactant)</b>  <u>Indication</u> - Prevention and treatment of Respiratory Distress Syndrome (RDS) in premature infants.	Ross Laboratories	09-29-89
<b>Retrovir (zidovudine)</b>  <u>Indication</u> - Treatment of pediatric patients with HIV disease.	Burroughs Wellcome	10-26-89
<b>Ceredase (beta-glucocerebrosidase)</b>  <u>Indication</u> - Chronic enzyme replacement therapy in the management of patients with Gaucher's disease (Type 1). [Charges]	Genzyme Corporation	11-07-89
<b>Fludarabine phosphate</b>  <u>Indication</u> - Chronic lymphocytic leukemia.	National Cancer Institute	11-24-89
<b>Baclofen Intrathecal</b>  <u>Indication</u> - Spasticity in patents with multiple sclerosis or spinal cord injury who are intolerant to or unresponsive to oral baclofen (03/90) and spasticity of cerebral origin (12/94).	Medtronic, Inc.	03-07-90 and 12-12-94

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<b>Granulocyte Macrophage Colony Stimulating Factor (GMCSF)</b>  <u>Indication</u> - Bone-marrow transplantation graft delay or failure.	Immunex Corp.	09-24-90
<b>Dideoxycytidine (ddC)</b>  <u>Indication</u> - Treatment of patients with AIDS or advanced ARC who cannot be maintained on zidovudine (AZT).	Hoffmann-LaRoche	05-30-91
<b>4-Hydroperoxycyclophosphamide (4HC)</b>  <u>Indication</u> - Bone marrow purging. [Charges]	Nova Pharmaceutical	06-14-91
<b>Oxandrolone</b>  <u>Indication</u> - Clinical management of boys with constitutional delay of growth and puberty (10/91) and in girls with Turners Synodrome (10/92). [Charges]	Gynex, Inc.	10-17-91 and 10-21-91
<b>Mepron (Atovaquone)</b>  <u>Indication</u> - Treatment of AIDS patients with Pneumocystis carinii pneumonia who are intolerant to or unresponsive to trimethoprim/sulfamethoxazole.	Burroughs Wellcome	11-08-91
<b>Cognex (Tacrine) (THA)</b>  <u>Indication</u> - Treatment of patients with Alzheimer's dementia. [Charges]	Parke-Davis	12-02-91

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<b>Mycobutin (Rifabutin)</b>  <u>Indication</u> - Prophylaxis against Mycobacterium Avium Complex bacteremia in HIV-infected patients.	Adria Laboratories	03-06-92
<b>2-Chlorodeoxyadenosine (2-CdA)</b>  <u>Indication</u> - Treatment of active Hairy Cell Leukemia.	National Cancer Institute	03-06-92
<b>Taxol</b>  <u>Indication</u> - Treatment of advanced refractory epithelial ovarian cancer.	National Cancer Institute	07-15-92
<b>Copolymer-1 (COP-1)</b>  <u>Indication</u> - Treatment of exacerbating-remitting Multiple Sclerosis. [Charges]	Teva/Lemmon	01-05-93
<b>Glucophage (Metformin HCl)</b>  <u>Indication</u> - Non-insulin dependent Diabetes Mellitus. [Charges]	Lipha	09-10-93
<b>Navelbine (Vinorelbine tartrate)</b>  <u>Indication</u> - Non-small cell lung cancer.	Burroughs Wellcome	04-14-94
<b>Somatropin</b>  <u>Indication</u> - Treatment of AIDS-associated catabolism/weight loss. [Charges]	Serono	12-20-94

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<b>Gemcitabine Hydrochloride</b>  <u>Indication</u> - Locally advanced or metastatic pancreatic cancer.	Lilly	01-27-95
<b>Atorvastatin</b>  <u>Indication</u> - Homozygous familial hypercholesterolemia or severe refractory hypercholesterolemia.	Parke-Davis	02-09-95
<b>Riluzole</b>  <u>Indication</u> - Amyotrophic Lateral Sclerosis (ALS).	Rhone-Poulenc Rorer	06-20-95
<b>Vistide (Cidofovir)</b>  <u>Indication</u> - Treatment of CMV Retinitis	Gilead Sciences, Inc.	09-01-95
<b>Autologous Peripheral Blood Lymphocytes Activated Ex Vivo with OKT3 Monoclonal Antibody</b>  <u>Indication</u> - Treatment of Metastatic (Stage IV) Renal Cell Carcinoma. [Charges]	Cellcor	09-15-95
<b>Carmustine Wafer</b>  <u>Indication</u> - Recurrent malignant glioma. [Charges]	Guilford Pharmaceuticals	10-27-95
<b>Myotrophin</b>  <u>Indication</u> - Amyotrophic Lateral Sclerosis (ALS).	Cephalon, Inc.	06-19-96

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Progesterone Gel		
<u>Indication</u> - Invitro Fertilization (IVF).	Columbia Research, Inc.	02-07-97